<center>**REMARKS**</center>

Claims 1-27 are pending in the application.

Claims 1-8 and 10-27 are amended above to overcome the examiner's Section 112 and/or Section 101 rejections.

No new matter has been added to the application by way of these specification and claim amendments.

I. THE CLAIM OBJECTIONS

The examiner objected to claims 19, 21-22, 24 and 26 for including typographical errors.

Claims 19, 21-22, 24 and 26 are amended above to correct the typographical errors.

II. THE SECTION 112, FIRST AND SECOND PARAGRAPH REJECTIONS

A. The Rejection Of Claims 10-18

The examiner rejected claims 10-18 under 35 U.S.C. 112, first and second paragraphs for attempting to define a machine entirely by its function.

These rejections are overcome by amending the rejected independent claims to include several machine elements including a microscope, camera and a computer apparatus. Support for these apparatus elements is found in the specification at least at page 11 lines 1-3 and page 18 lines 21-28 of the specification.

B. The Rejection Of Claims 19-27

The examiner rejected claims 19-27 under the first paragraph of section 112 for failing to comply with the written description requirement.

The rejection is overcome by amending the relevant claims to delete references to a "computer software product".

The examiner also rejected claims 19-27 for being unclear. In particular, the examiner is unclear whether patentable weight should be given to certain terms.

The examiner's rejection is overcome by adding language to the claims that makes it clear that the instructions provide for control of the computer apparatus to carry out the relevant steps.

III. THE SECTION 101 REJECTION

The examiner rejected claims 1-9 under 35 U.S.C. 101 for failure to recite subject matter that falls within one of the four statutory categories of invention.

The rejection is overcome by amending the claims to recite using a computer apparatus to perform one or more of the claimed methods. Support for these amendments is found at least at page 12 lines 13-14 and page 12 lines 13-14 of the specification.

IV.   THE ANTICIPATION REJECTIONS

A.   The Bacus Anticipation Rejection

The examiner rejected claims 10-27 for being anticipated by Bacus (USP 5,008,185).

In order for a reference to anticipate, the reference must show the same invention in as complete a detail as claimed. *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Moreover, the elements must be arranged in the reference as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). Claims 10-127 are novel and patentable because Bacus does not disclose the elements of the claimed invention arranged as claimed.

Claims 10-18 are currently directed to a system that includes a computer apparatus including a program stored in a memory that causes the computer to perform certain function. Claims 19-27 are directed to computer hardware medium including computer readable instructions that cause a computer to perform certain functions.

The Examiner states that the computer apparatus disclosed by Bacus is fully capable of performing the claimed functions if suitably programmed to do so and therefore meets the claims. The examiner thus appears to be improperly reading one of the claim limitations into Bacus because Bacus does not disclose a computer that includes memory or hardware that includes a program that directs the computer as claimed. Instead, Bacus disclose an operator-computer interactive process that requires "interactive responses by the operator and menu selections on different instruction screens" - col. 9, lines 23-25.

The examiner admits that Bacus does not disclose an apparatus that is so programmed when the examiner takes the position that Bacus discloses an apparatus that is "capable of performing the intended use . . . if suitably programmed to do so. . . ". Indeed, regarding claims 19-27, the Examiner states that "the claim language is such that the recited functions are a

recitation of intended use for the claimed computer software product". The examiner further states that "While the functions of apparatus, in accordance with the instructions, disclosed by Bacus, are not necessarily the same as those recited in claims 19-27, the computer program product comprising a computer readable hardware medium containing computer readable instructions disclosed by Bacus provides sufficient functionality to the computer that would enable the claimed functions to be performed.

The claims are amended above link the programmed functions to a structure. For example, claims 19-27 are amended to specify that the computer readable hardware medium embodies the computer readable instructions as stated in Applicant's specification at page 18 lines 22-23. This means that putting the computer readable instructions on to the computer readable hardware medium changes it physically. Contrary to the Examiner's statement in this regard as above, Bacus does not disclose a computer readable hardware medium containing computer readable instructions providing sufficient functionality to the computer that would enable the claimed functions to be performed. As a result Bacus does not anticipate any of claims 10-27 because it does not disclose all of the features of any one of claims 10-27 arranged as claimed.

B. The De La Torre-Bueno Anticipation Rejection

Claims 1, 2, 10, 11, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,697,509 to De La Torre-Bueno. The Examiner states that De La Torre-Bueno discloses the method claimed in claim 1 of scoring Oestrogen and Progesterone Receptors expression (ER and PR). The examiner's position is respectfully traversed as being factually incorrect because what De La Torre-Bueno actually discloses is measurement of a totally different parameter, Her2NU (also known as C-erb-2, Cerb-B2, her-2, her-2/neu and erb-2) – see e.g. col. 1 line 37. For this reason alone claims 1-2, 10-11 and 19-20 are novel and patentable over De La Torre-Bueno.

The Examiner goes on to state that De La Torre-Bueno discloses obtaining the number of relatively dark pixels having intensities below a predetermined intensity threshold, and cites col. 3, line 4 - col. 4, line 13, pixel counter for unmasked pixels. Here again, the examiner misunderstands what the reference teaches. De La Torre-Bueno does not use the number of relatively dark pixels. Instead, a region of tumor in a specimen is user-selected with a computer mouse. (See De La Torre-Bueno at col. 2 lines 58-61). Then the blue colour value of each pixel

in the selected region is subtracted from the average blue value of the background. The differences are added and divided by the number of pixels in the selected region to give a mean value for DAB for conversion to a number in the range 0 to 3. (See De La Torre-Bueno at col. 4 lines 5-19). Consequently De La Torre-Bueno is concerned with pixel blueness not pixel darkness. Claims 1-2, 10-11 and 19-20 are novel for this reason as well because De La Torre-Bueno does not identically disclose the claimed invention.

The Examiner then states that De La Torre-Bueno discloses scoring ER or PR in accordance with the magnitude of the number so obtained. As mentioned above, what De La Torre-Bueno actually discloses is measurement of a totally different parameter, i.e. Her2NU not ER or PR. Moreover, De La Torre-Bueno does not measure Her2NU from the magnitude of the number of dark pixels, but instead from an average of blue pixel value differences between tumor region and background.

Consequently De La Torre-Bueno fails to anticipate claim 1 on three different counts, wrong parameter, wrong pixel type and wrong calculation. Similar remarks apply to claims 10 and 19 which have similar subject matter.

Regarding claims 2, 11 and 20, these are equivalent to claims 1, 10 and 19 respectively with the addition of image data transformation to a different image space having an intensity image plane. Consequently De La Torre-Bueno cannot anticipate claims 2, 11 and 20 on the same three different counts - wrong parameter, wrong pixel type and wrong calculation.

V.   THE OBVIOUSNESS REJECTION

Claims 4, 5, 13, 14, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacus in view of "Computer-Aided Detection of Breast Cancer Nuclei" to Schnorrenberg et al. ("Schnorrenberg").

Regarding claims 4, 13 and 22, the Examiner indicates that Bacus discloses a method of scoring ER and PR by determining brown blob area as a proportion of total blob area and scoring ER or PR in accordance with the brown blob area proportion. (Citing col. 5, lines 33-55, col. 13, lines 11-16, and col. 14, lines 54-62 of Bacus). The examiner's rejection is respectfully traversed. Although Bacus mentions distinguishing brown blobs (nuclear area) from total blobs at col. 13, lines 11-16, and measuring brown blob optical density at col. 14 lines 50-53, there is

no disclosure of scoring ER or PR from brown blob area proportion. Instead, at col. 5, lines 33-55 and also col. 15 lines 34-50, Bacus makes it clear that the score is a product of percentage (%) positively stained multiplied by staining intensity and divided by an empirical scaling factor N. Moreover, Bacus does not disclose an automated technique, but instead as previously stated discloses an operator-computer interactive process which is not automated.

Applicant's invention as claimed in claims 4, 13 and 22 is based on Applicant's discovery that ER and PR can be scored from brown blob area proportion without measuring any other parameter such as staining intensity. This discovery lends itself to automation and (as now claimed in amended claims 4, 13 and 22) to use of a computer to carry out steps which are done at least partly manually by Bacus. Applicant's invention as claimed in claim 4, 13 and 22 is simpler than Bacus, but simplicity is no bar to invention or patentability.

The Examiner acknowledges that Bacus is silent with regard to determining brown blob area proportion thresholds to quantify scoring, and is therefore silent with regard to comparing the brown blob area proportion with the brown blob area proportion thresholds and scoring ER or PR in accordance therewith. But the Examiner states that Schnorrenberg discloses a computer aided detection system of breast cancer nuclei in which scoring is based on the proportion of positive nuclei. The Examiner also states that Schnorrenberg discloses an HSCORE technique wherein proportion thresholds are determined to quantify scoring and observed proportion values are compared to the proportion thresholds, and scoring ER or PR in accordance therewith. This rejection is respectfully traversed for similar reasons as stated above in connection with Bacus. Schnorrenberg does not disclose comparing the brown blob area proportion with the brown blob area proportion thresholds and scoring ER or PR in accordance therewith as presently claimed.

Instead, Schnorrenberg makes it clear that the score is derived by summing over various degrees of staining a set of products or sub-scores each having of two components, one relating to percentage (%) of nuclei and the other to degree of staining. (See page 137 Figure 8(b)). The percentage component is the actual percentage divided by 20 and the staining component is a value from 0 to 5 depending on whether the nuclei are negative, or weakly to very strongly stained. Consequently Schnorrenberg fails to remedy the deficiencies of Bacus, and this combination does not anticipate claims 4, 13 and 22.

Regarding claims 5, 14 and 23, these are similar to claims 4, 13 and 22 with the addition of (i) remapping pixel intensities in the image data to increase the contrast of relatively darker image regions and to transform relatively brighter image regions into a contrast free background and (ii) converting the remapped image data into image data corresponding to thresholded binary images form which total blob area and brown blob area are discernible respectively. Bacus therefore fails to render claims 5, 14 and 23 obvious for the reasons given in relation to claims 4, 13 and 22.

Regarding claim 5, the Examiner takes the position that Bacus discloses remapping step (i) and converting step (ii) above citing Bacus at col. 10, lines 51-64; col. 12, lines 10-63; col. 13, line 30 - col. 14, lines 41. Applicant has carefully studied these cited Bacus extracts, and they do not disclose remapping step (i) or converting step (ii). Instead:

a) Bacus col. 10, lines 51-64 discloses using colour filters to obtain two monochromatic images;

b) Bacus col. 12, lines 10-63 discloses the dual colour filtering technique of col. 10, lines 51-64 in more detail; and

c) Bacus col. 13, line 30 - col. 14, lines 41 discloses calibration of the measurement process using thresholds.

None of these three extracts has anything whatsoever either to do with remapping pixels to increase the contrast of relatively darker image regions or to do with converting the remapped image data into image data corresponding to thresholded binary images. As a result, claim 5 is not obvious and patentable for at least this reason. Similar remarks apply to claims 14 and 23.

Claims 6, 15, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bacus and Schnorrenberg as applied to claims 4, 13 and 22 above, and further in view of De La Torre-Bueno. This is respectfully traversed at least because the combination of Schnorrenberg and Bacus does not anticipate claims 4, 13 and 22 for reasons given above.

In addition, the Examiner indicates that De La Torre-Bueno renders claims 6, 15, 24 and 25 unpatentable for the reasons the Examiner gave in relation to claims 1, 2, 10, 11, 19 and 20. This is respectfully traversed because De La Torre-Bueno fails to anticipate claims 1, 2, 10, 11, 19 and 20 for the reasons given above in detail in relation to claim 1, i.e. in brief De La Torre-Bueno is deficient on three different counts, wrong parameter, wrong pixel type and wrong calculation.

Regarding claim 25, contrary to the Examiner's remarks, the combination of Bacus, Schnorrenberg and De La Torre-Bueno does not disclose obtaining the number of relatively dark pixels having intensities below a predetermined intensity threshold. As previously stated, De La Torre-Bueno does not use the number of relatively dark pixels. Instead, the blue colour value of each pixel in a user-selected tumor region is subtracted from the background blue value, and the differences are then averaged. Consequently De La Torre-Bueno is concerned with pixel blueness not darkness.

Claims 7, 8, 16, 17 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Bacus, Schnorrenberg and De La Torre-Bueno. The Examiner states that claims 7, 8, 16, 17 and 26 are drawn to various combinations of elements previously addressed in the rejection of other claims. Consequently, these claims are patentable for at least the same reasons presented above in support of the novelty and non-obviousness of claims 4, 5, 6, 13, 14, 15, 22, 23, 24 and 25 above.

CONCLUSION

All pending application claims are believed to be ready for patenting for at least the reasons recited above. Favorable reconsideration and allowance of all pending application claims is courteously solicited.

Date: June 18, 2009   By: __/A. Blair Hughes/_____
                                               A. Blair Hughes
                                               Reg. No. 32,901
                                               312-913-2123
                                               hughes@mbhb.com